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1103326-0660

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No: 6,946,157 B2  
Issued: Sept. 20, 2005  
Name of Patentee: Folestad et al.  
Title of Invention: Method and Apparatus for Monitoring the Coating on Particle During Manufacturing of a Pharmaceutical Product  
Serial No.: 09/806,795  
Examiner: Elena Tsoy  
Art Unit: 1762

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8	
I hereby certify that this paper is being deposited with the United States Postal Service as first class mail on the date indicated below in an envelope addressed to: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.	
<u>Andrew Fessak</u>	<u>48,528</u>
Agent Name	PTO Reg. No.
<u>Andrew Fessak</u>	<u>10/19/05</u>
Signature	Date of Signature

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Certificate  
OCT 26 2005  
of Correction

REQUEST FOR CERTIFICATE OF CORRECTION OF PATENT  
FOR PTO MISTAKE [37 C.F.R. §1.322(a)]

1. It is noted that a printing error appears in the referenced patent which is attributable to the Office.
2. The location where the error(s) is/are shown correctly in the application file is:

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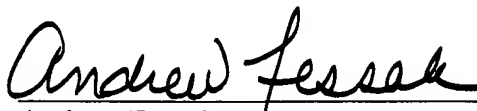
<b>Column and Line Number of Issued Patent</b>	<b>Location in Application File Where the Error is Shown Correctly</b>
<u>Col. 8, line 6</u> “preformed” should read --performed--.	Letter to Examiner, July 21, 2005 (Original claim 2, page 1)
<u>Col. 8, line 7</u> “pert” should read --part--.	Letter to Examiner, July 21, 2005 (Original claim 2, page 1)
<u>Col. 8, line 10</u> “eta” should read --of a--.	Letter to Examiner, July 21, 2005 (Original claim 4, page 1)
<u>Col. 9, line 54</u> “winging” should read --arranging--.	Letter to Examiner, July 21, 2005 (Original claim 24, page 4)
<u>Col. 9, line 63</u> Insert a comma after --particle--.	Letter to Examiner, July 21, 2005 (Original claim 24, page 4)
<u>Col. 9, line 67</u> “measurements” should read --measurement--.	Letter to Examiner, July 21, 2005 (Original claim 25, page 4)
<u>Col. 10, line 23</u> “from” should read --from the--.	Letter to Examiner, July 21, 2005 (Original claim 32, page 5)
<u>Col. 10, line 44</u> “of” should read --of a--.	Letter to Examiner, July 21, 2005 (Original claim 35, page 5)
<u>Col. 11, line 15</u> “flow” should read --gas flow--.	Letter to Examiner, July 21, 2005 (Original claim 42, page 6)
<u>Col. 12, line 5</u> “a capsule” should read --or a capsule--.	Letter to Examiner, July 21, 2005 (Original claim 48, page 7)

3. Attached is a copy of Form PTO/SB/44 (also Form PTO-1050).
4. Please send the Certificate to the undersigned Agent.
5. Patentees request that the issuance of a Certificate of Correction be expedited in accordance with the PTO’s policy for expediting issuance of Certificates of Correction, as outlined in the PTO notice, issued August 21, 2002 entitled “Expedited Issuance of Certificates of Correction when the Error is Attributable to the United States Patent and Trademark Office”. In support of the requested correction, Patentees are attaching copies of the relevant pages from the application file with this Request.

6. No fee should be due in connection with this communication. However, if a fee is deemed to be due, the Commissioner is authorized to charge such fee to Deposit Account No. 23-1703.

Dated: Oct. 19, 2005

Respectfully submitted,



Andrew Fessak

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Enclosures

**UNITED STATES PATENT AND TRADEMARK OFFICE  
CERTIFICATE OF CORRECTION**Page 1 of 1PATENT NO. : 6,94<sup>6</sup>~~00~~,157 B2

APPLICATION NO.: 09/806,795

ISSUE DATE: : Sept. 20, 2005

INVENTOR(S) : Folestad et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

- Col. 8, line 6: "preformed" should read --performed--.
- Col. 8, line 7: "pert" should read --part--.
- Col. 8, line 10: "eta" should read --of a--.
- Col. 9, line 54: "winging" should read --arranging--.
- Col. 9, line 63: Insert a comma after --particle--.
- Col. 9, line 67: "measurements" should read --measurement--.
- Col. 10, line 23: "from" should read --from the--.
- Col. 10, line 44: "of" should read --of a--.
- Col. 11, line 15: "flow" should read --gas flow--.
- Col. 12, line 5: "a capsule" should read --or a capsule--.

**MAILING ADDRESS OF SENDER (Please do not use customer number below):**

Andrew Fessak  
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This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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# FACSIMILE

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**Date:** 21 July 2005

**No. of Pages (including cover):** 8

**To:** Examiner Elena Tsoy  
USPTO

**Fax Number:** 571-273-1429  
**Contact Number:**

**From:** John M. Genova

**Reference No.:** 1103326-0660

**Re:** U.S. Patent Appln. Serial No. 09/806,795

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Dear Examiner Tsoy:

Further to your telephone call of 18 July 2005 in connection with the referenced application, I am sending you a complete set of the allowed claims which shows the amendments to claims 16-20, 23 and 37-41 to remove a dependency on a higher numbered claim. For the record, Applicants submit that the amendments to the allowed claims were made for formal reasons and not for reasons relating to the patentability of the claimed invention.

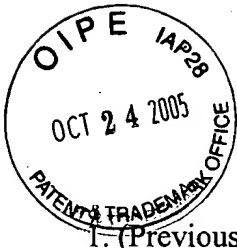
Sincerely,



John M. Genova  
Reg. No. 32,224

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OCT 27 2005



U.S. PATENT APPLICATION SERIAL NO. 09/806,795

AMENDED ALLOWED CLAIMS

1. (Previously presented) A method for monitoring the formation of a coating on a single particle, comprising the steps of:
  - (a) arranging the particle at a given spatial location, wherein the step of arranging the particle comprises fluidizing the particle on an upwardly directed gas flow;
  - (b) forming the coating on the particle at the given spatial location; and
  - (c) performing a spectroscopic measurement on the coating while the coating is being formed on the particle to obtain a measurement value of at least one principal parameter related to the coating.
2. (Previously presented) The method as set forth in claim 1, wherein the spectrometric measurement is performed continuously during at least part of the coating formation step to generate a sequence of measurement values of the principal parameter.
3. (Canceled)
4. (Previously presented) The method as set forth in claim 1, wherein the coating formation comprises generating a single droplet of a coating fluid, and bringing the droplet to impinge upon the particle.
5. (Previously presented) The method as set forth in claim 4, wherein the droplet upon generation is moved into and allowed to follow the upwardly directed gas flow to the particle.
6. (Previously presented) The method as set forth in claim 4, wherein the step of generating a single droplet is repeated, thereby forming at least one stream of droplets which sequentially impinge upon the particle.
7. (Previously presented) The method as set forth in claim 1, further comprising the steps of: monitoring at least one control parameter related to the particle or its environment; and identifying a functional relationship between the control parameter and the principal parameter.
8. (Previously presented) The method as set forth in claim 7, further comprising the step of generating an aggregate model for prediction of the influence of the control parameter on the

principal parameter for a large number of particles based on the functional relationship for the single particle.

9. (Previously presented) The method as set forth in claim 7, further comprising the step of adjusting the control parameter at least partly on the basis of the measurement value.

10. (Previously presented) The method as set forth in claim 1, further comprising the steps of:  
a) monitoring at least one control parameter related to the particle or its environment; and  
b) identifying a functional relationship between the control parameter and the principal parameter,

wherein the control parameter comprises a property of the gas flow.

11. (Previously presented) The method as set forth in claim 7, wherein the control parameter comprises a property of the particle.

12. (Previously presented) The method as set forth in claim 4, further comprising the steps of:  
monitoring at least one control parameter related to the particle or its environment; and  
identifying a functional relationship between the control parameter and the principal parameter,  
wherein the control parameter comprises a property of the droplet.

13. (Previously presented) The method as set forth in claim 4, further comprising the steps of:  
monitoring at least one control parameter related to the particle or its environment; and  
identifying a functional relationship between the control parameter and the principal parameter;  
wherein the control parameter comprises the duration of a wetting period during the coating formation step.

14. (Previously presented) The method as set forth in claim 4, further comprising the steps of:  
monitoring at least one control parameter related to the particle or its environment; and  
identifying a functional relationship between the control parameter and the principal parameter,  
wherein the control parameter comprises the duration of a drying period during the coating formation step.

15. (Previously presented) The method as set forth in claim 1, wherein the step of obtaining the measurement value comprises:

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- c1) generating a sample vector of measurement data from the spectrometric measurement; and
- c2) condensing the measurement data into the measurement value of the principal parameter.

16. (Currently amended) The method as set forth in any one of claims 1, 2 [,] **and** 4-15 [and 42-47], wherein the spectrometric measurement is performed by means of near-infrared spectrometry.

17. (Currently amended) The method as set forth in any one of claims 1, 2 [,] **and** 4-15 [and 42-47], wherein the spectrometric measurement is performed by means of a spectrometric method based on Raman scattering.

18. (Currently amended) The method as set forth in any one of claims 1, 2 [,] **and** 4-15 [and 42-47], wherein the spectrometric measurement is performed by means of a spectrometric method based on absorption in the UV, visible, or infrared (IR) wavelength region, or luminescence or fluorescence emission.

19. (Currently amended) The method as set forth in any one of claims 1, 2 [,] **and** 4-15 [and 42-47], wherein the spectrometric measurement is performed by means of imaging spectrometry.

20. (Currently amended) The method as set forth in any one of claims 1, 2 [,] **and** 4-15 [and 42-47], wherein the particle is a pharmaceutical product.

21. (Canceled)

22. (Previously presented) A method for controlling the coating process of a batch of particles, comprising the steps of:

- a) monitoring the coating formation according to claim 2;
- b) using the sequence of measurement values of the principal parameter as a sequence of reference values in the control; and
- c) obtaining a corresponding spectroscopic measurement on the batch of particles to provide a sequence of actual values for the control.

23. (Currently amended) A method for controlling the coating process of a batch of particles, comprising the steps of:

- a) monitoring the coating formation according any one of claims 1, 2 [,] **and** 4-15 [and 42-47];

- b) identifying a functional relationship between at least one principal parameter and at least one simultaneously-monitored control parameter, wherein the control parameter is related to an environment of a single particle of the batch;
- c) selecting one or more control parameters, based on the functional relationship, to represent one or more of the principal parameters;
- d) determining a desired sequence of values of the selected control parameter(s) for the single particle; and
- e) controlling the coating process of the batch of particles based on the desired sequence of selected control parameter values.

24. (Previously presented) An apparatus for monitoring the formation of a coating on a single particle comprising:

means for arranging the particle at a given spatial location, wherein the means comprises a flow unit which generates a fluidized gas flow upon which the particle is fluidized;

a fluid supply unit for applying a coating fluid to the particle to form a coating at the given spatial location; and

a measurement unit which performs a spectrometric measurement on the coating while the coating is being formed on the particle, and derives a measurement value of at least one principal parameter related to the coating.

25. (Previously presented) The apparatus as set forth in claim 24, wherein the measurement unit continuously performs the spectrometric measurement and thereby generates a sequence of measurement values of the principal parameter.

26. (Canceled)

27. (Previously presented) The apparatus as set forth in claim 24, further comprising a chamber in which the coating is formed on the particle, wherein the flow unit provides a shielding gas inside the chamber intermediate the measurement unit and the location of the particle, and wherein the shielding gas is substantially identical to the gas used for fluidizing the particle.

28. (Previously presented) The apparatus as set forth in claim 24, wherein the fluid supply unit generates a single droplet of the coating fluid which is brought to impinge upon the particle.

29. (Previously presented) The apparatus as set forth in 28, wherein the fluid supply unit injects each droplet of the coating fluid into the fluidizing gas flow.

30. (Previously presented) The apparatus as set forth in claim 28, wherein the fluid supply unit repeatedly generates single droplets of the coating fluid and thereby forms a stream of such droplets which sequentially impinge upon the particle.

31. (Previously presented) The apparatus as set forth in claim 24, further comprising a control unit which monitors at least one control parameter related to the particle or its environment.

32. (Previously presented) The apparatus as set forth in claim 31, wherein the control unit receives the measurement value from the measurement unit and adjusts the control parameter at least partly on the basis of the measurement value.

33. (Previously presented) The apparatus as set forth in claim 31, wherein the control unit receives the measurement value from the measurement unit and adjusts the control parameter at least partly on the basis of the measurement value; and wherein the control parameter comprises a property of the fluidizing gas flow, and the control unit adjusts the control parameter by controlling the flow unit.

34. (Previously presented) The apparatus as set forth in claim 31, wherein the control unit receives the measurement value from the measurement unit and adjusts the control parameter at least partly on the basis of the measurement value; and wherein the control parameter comprises a property of the droplet, and the control unit adjusts the control parameter by controlling the fluid supply unit.

35. (Previously presented) The apparatus as set forth in claim 31, wherein the control unit receives the measurement value from the measurement unit and adjusts the control parameter at least partly on the basis of the measurement value; and wherein the control parameter comprises the duration of a droplet generation period; and the control unit adjusts the control parameter by controlling the fluid supply unit.

36. (Previously presented) The apparatus as set forth in claim 31, wherein the control unit receives the measurement value from the measurement unit and adjusts the control parameter at

least partly on the basis of the measurement value; and wherein the control parameter comprises the duration of a drying period, and the control unit adjusts the control parameter by controlling the fluid supply unit.

37. (Currently amended) The apparatus as set forth in any one of claims 24, 25 [,] **and** 27-36 [and 49-52], wherein the measurement unit performs the spectrometric measurement by means of near-infrared spectrometry.

38. (Currently amended) The apparatus as set forth in any one of claims 24, 25 [,] **and** 27-36 [and 49-52], wherein the measurement unit performs the spectrometric measurement by means of a spectrometric method based on Raman scattering.

39. (Currently amended) The apparatus as set forth in any one of claims 24, 25 [,] **and** 27-36 [and 49-52], wherein the measurement unit performs the spectrometric measurement by means of a spectrometric method based on absorption in the UV, visible, or infrared (IR) wavelength region, or luminescence or fluorescence emission.

40. (Currently amended) The apparatus as set forth in any one of claims 24, 25 [,] **and** 27-36 [and 49-52], wherein the measurement unit performs the spectrometric measurement by means of imaging spectrometry.

41. (Currently amended) The apparatus as set forth in any one of claims 24, 25 [,] **and** 27-36 [and 49-52], wherein the particle is a pharmaceutical product.

42. (Previously presented) The method as set forth in claim 5, further comprising the steps of:  
a) monitoring at least one control parameter related to the particle or its environment; and  
b) identifying a functional relationship between the control parameter and the principal parameter,

wherein the control parameter comprises a property of the gas flow.

43. (Previously presented) The method as set forth in claim 10, wherein the property of the gas flow is flow rate, temperature, or solvent content.

44. (Previously presented) The method as set forth in claim 42, wherein the property of the gas flow is flow rate, temperature, or solvent content.

45. (Previously presented) The method as set forth in claim 11, wherein the property of the particle is size, shape, density, or porosity.
46. (Previously presented) The method as set forth in claim 12, wherein the property of the droplet is size, generation rate, or concentration of a constituent.
47. (Previously presented) The method as set forth in claim 13, wherein the wetting period is effected by controlling the droplet generation.
48. (Previously presented) The method as set forth in claim 20, wherein the pharmaceutical product is a pellet, a tablet, or a capsule.
49. (Previously presented) The apparatus as set forth in claim 31, wherein the control unit receives the measurement value from the measurement unit and adjusts the control parameter at least partly on the basis of the measurement value; and wherein the control parameter comprises a property of the fluidizing gas flow, and the control unit adjusts the control parameter by controlling the flow unit.
50. (Previously presented) The apparatus as set forth in claim 33, wherein the property of the fluidizing gas flow is flow rate, moisture content, or temperature.
51. (Previously presented) The apparatus as set forth in claim 49, wherein the property of the fluidizing gas flow is flow rate, moisture content, or temperature.
52. (Previously presented) The apparatus as set forth in claim 34, wherein the property of the droplet is size, generation rate, or concentration of a constituent.
53. (Previously presented) The apparatus as set forth in claim 41, wherein the pharmaceutical product is a pellet, tablet, or capsule.